

Remarks

Upon entry of the amendments, claims 1-3, 6 and 11-22 and 24 are pending.

Amendments To The Claims

Claims 1, 6, 11, 12 and 24 have been amended. Claims 4, 5, 7-10 and 23 have been canceled.

Claim 1 has been amended to recite a method of diagnosing a pre-cancerous condition. The amendment is supported by original claim 1.

Claims 6 has been amended to depend from claim 1 rather than claim 5. Claim 11 has been amended to depend from claim 3 rather than claim 10. Claims 12 and 24 have been amended to depend from claim 1 rather than claim 4. The amendments are supported by the claims as originally filed.

No new matter has been added by way of these amendments. Accordingly, entry of the amendments is respectfully requested. These amendments are made without prejudice and are not to be construed as abandonment of the previously claimed subject matter.

Rejections Under 35 U.S.C. § 102(e)

1. Claims 1-12, 23 and 24 stand rejected under 35 U.S.C. § 102 (e) as being anticipated by Sun *et al.* (PCT Publication Number WO2004/045544; hereinafter Sun).

Applicant respectfully traverses the rejection.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Independent claim 1 is directed to a method of diagnosing a pre-cancerous condition comprising using an anti-PCDGF antibody. Claims 2, 3, 6, 11, 12 and 24 depend from claim 1 and incorporate its recitation by reference (35 U.S.C. § 112 paragraph 4). Claims 4, 5, 7-10 and 23 have been canceled rendering their rejection moot.

Applicants respectfully submit that Sun does not teach or suggest a method of diagnosing a pre-cancerous condition. Sun at best merely suggests a method of

diagnosing cancer comprising using an anti-PCDGF antibody (*see*, e.g. paragraph 20 of the specification: “the degree of PCDGF overexpression directly correlates with the degree of tumorigenicity [of a cell].”) Applicant submits that Sun uses the term “tumorigenic cell” interchangeably with “cancer cell.” For example, in paragraph 43 of the specification, Sun used the example of an anti-PCDGF receptor antibody stained breast cancer tissue sample to support the statement that “anti-PCDGF receptor antibodies are capable of binding to tumorigenic cells but not to normal cells.” In Example 7, Sun provides additional examples of cancer cells preferentially bound by PCDGF or anti-PCDGF antibodies. Based on its teachings, one of skill in the art is therefore compelled to conclude that Sun uses the terms “tumorigenic cell” and “cancer cell” interchangeably. Therefore the diagnostic method suggested by Sun’s teaching is limited to the diagnosis of cancer and does not include the diagnosis of a pre-cancerous condition.

Because a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference, and Sun does not teach or suggest a method of diagnosing a pre-cancerous condition as recited in rejected claims 1-3, 6, 11, 12, 23 and 24, Applicant respectfully requests withdrawal of this rejection.

2. Claims 1-24 stand rejected under 35 U.S.C. § 102 (e) as being anticipated by Kiener *et al.* (PCT Publication Number WO2005/000207, hereinafter “the ‘207 application”).

Applicant respectfully traverses the rejection.

[T]he invention was described in - (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent . . . except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

35 U.S.C. § 102(e)(emphasis added).

Applicant respectfully submits that the ‘207 application is not available as prior art to the instant application because the subject matter relied on in the rejection was not invented by “another.” A declaration of the inventor under C.F.R. § 1.132 accompanies this response. In the declaration Michael S. Kinch, the sole inventor of the present

application states that he is the sole inventor of the subject of increased PCDGF expression in precancerous conditions disclosed but not claimed in the '207 application. Therefore, the '207 application is not available as prior art to the instant application.

Because the '207 application relied on in the rejection is not available as prior art to the instant application, Applicant respectfully requests withdrawal of this rejection.

3. Claims 1-12, 23 and 24 stand rejected under 35 U.S.C. § 102 (e) as being anticipated by Serrero (US Patent Publication 2003/0108950).

Applicant respectfully traverses the rejection.

Independent claim 1 is directed to a method of diagnosing a pre-cancerous condition. Claims 2, 3, 6, 11, 12 and 24 depend from claim 1 and incorporate its recitation by reference (35 U.S.C. § 112 paragraph 4). Claims 4, 5, 7-10 and 23 have been canceled rendering their rejection moot.

Applicant respectfully submits that Serrero does not teach a method of diagnosing a pre-cancerous condition. Serrero at best merely teaches a method of diagnosing cancer. Serrero uses the term "tumorigenic cell" interchangeably with "cancer cell." First, Serrero teaches that cancer diagnosis often requires testing whether a tissue sample is tumorigenic and that there is a need for improved detection of the presence of tumorigenic cancer cells in biopsies (*see*, paragraphs 0010 and 0011). Second, Serrero teaches an *in vivo* assay to determine the tumorigenicity of a cell population (*see*, paragraph 0077). This, and similar *in vivo* assays were developed to detect the tumorigenicity of cancer cells. Cell lines derived from pre-cancerous lesions are non-tumorigenic in these assays. Therefore, Serrero teaches a method of diagnosing cancer but does not teach a method of diagnosing a pre-cancerous condition.

Because a claim is anticipated only if each and every element as set forth in the claim is found in a single prior art reference, and Serrero does not teach a method of diagnosing a pre-cancerous condition as recited in rejected claims 1-12, 23 and 24, Applicant respectfully requests withdrawal of this rejection.

Rejections Under 35 U.S.C. § 103 (a)

1. Claims 1-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Sun *et al.* (PCT Publication Number WO2004/045544) in view of Kiener *et al.* (PCT Publication Number WO2005/000207, hereinafter "the '207 application").

2. Claims 1-24 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Serrero (US Patent Publication 2003/0108950) in view of Kiener *et al.* (PCT Publication Number WO2005/000207).

Applicant respectfully traverses these rejections.

To establish a *prima facie* case of obviousness, the Patent Office must show that the prior art reference (or references) teaches or suggests all the claimed limitations. *In re Vaeck*, 20 U.S.P.Q.2d 1438, 1442 (Fed. Cir. 1991); *Manual of Patent Examining Procedure*, § 2143.

As discussed above, independent claim 1 is directed to a method of diagnosing a pre-cancerous condition. Claims 2, 3, 6, 11-22 and 24 depend from claim 1. Claims 4, 5, 7-10 and 23 have been canceled rendering their rejection moot.

Applicant respectfully submits that the rejections under 35 U.S.C. § 103(a) must fail because the combinations of art relied on do not teach or suggest a method of diagnosing a pre-cancerous condition. First, as discussed above, the '207 application is not available as prior art to the instant application.

Second, Sun and Serrero, the remaining art cited in the first and second, respectively, rejections is not sufficient to establish a *prima facie* case of obviousness, because neither Sun nor Serrero teach or suggest a method of diagnosing a pre-cancerous condition. Both Sun and Serrero merely teach or suggest a method of diagnosing cancer.

Applicant respectfully submits that the *prima facie* case of obviousness must fail because the available art cited in support of the rejections under 35 U.S.C. § 103(a) does not teach or suggest all elements recited in claim 1-24: (a) the '207 application is not available as prior art against the instant application, and (b) Sun or Serrero alone does not teach or suggest a method of diagnosing a pre-cancerous condition. Therefore, Applicant respectfully requests withdrawal of the obviousness rejections of claims 1-24.

Respectfully submitted,

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